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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/038,069 | 12/21/2001 | Guiying Li | 01-019-A | 7326 |

7590

04/03/2003

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EXAMINER

HABTE, KAHSAY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,069

Applicant(s)

LI ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-210 is/are pending in the application.
- 4a) Of the above claim(s) 73-164 and 189-210 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-72 and 165-188 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: . |

DETAILED ACTION

Restriction/Election

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3 (in part) and 165 (in part), drawn to purines where **Z₂** and **Z₄** or **Z₁** and **Z₃** in the compound formula are nitrogens and the rest are carbons, classified in class 544, subclasses 264, 265, 269, 276 and 277.
 - II. Claims 1-3 (in part) and 165 (in part), drawn to fused 1,4-diazines where **Z₁** and **Z₄** in the compound formula are nitrogens and the rest carbons, classified in class 544, subclass 350.
 - III. Claims 1-3 (in part) and 165 (in part), drawn to fused 1,2-diazines where **Z₁** and **Z₂** or **Z₂** and **Z₃** or **Z₃** and **Z₄** in the compound formula are nitrogens and the rest carbons, classified in class 544, subclass 236.
 - IV. Claims 1-3 (in part), 73-164, 165 (in part), and 189-210 drawn to monoazines where one of **Z₁ - Z₄** in the compound formula is nitrogen and the rest carbons, classified in class 546, subclass 118.
 - V. Claims 1-3 (in part), 4-72, 165 (in part), and 183-188, drawn to benzoimidazoles where **Z₁ - Z₄** are all carbons, classified in class 548, subclass various.

The inventions are distinct, each from the other because of the following reasons:
Groups I-V are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of **Z₁ - Z₄** in the compound formula do not belong to

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the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. For example, Group I (purines) that belong to a recognized class of chemical compounds are different from Groups II-V, because the nitrogens are at 1,3-position of the six-membered ring. Group II and Group III are also different from Group I and Groups IV-V, because the nitrogens at 1,4 position of the six-membered ring (Group II) and the nitrogens at 1,2 position (Group III) are not present in other Groups. Group IV is drawn to monoazines (one nitrogen in the six-membered ring) and this feature is not present in Groups I-III or Group V. Group V is different from Groups I-IV, because the six-membered ring does not contain any heteroatom i.e. $Z_1 - Z_4$ are all carbons. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

In addition to Groups I-V, applicants are also required to elect a single method from the following methods:

Method (A) - claims 166-172 and 178-182, drawn to pharmaceutical methods.

Method (B)- claims 173-177, drawn to a method of demonstration for the presence of GABA_A receptor in a cell.

Methods A and B are different one from the other, since Method (A) are drawn to pharmaceutical methods (treating or altering signal-transducing activity of GABA

receptor) and are classified in class 514. Method B is different from Method A, because it is drawn to non-pharmaceuticals. Method B is drawn to a method of detection and is classified in different class than 514.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Steven Sarussi on March 10, 2003 a provisional election was made traverse to prosecute the invention of Group V and Method A, claims 1-3 (in part), 4-72, 165-182 (in part), and 183-188 (in part). Affirmation of this election must be made by applicant in replying to this Office action. Claims 73-164 and 189-210 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Objection

3. Claims 1-3 and 165-188 are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read

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on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-72 and 165-188 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 1 (page 254, lines 12 and 21) or elsewhere in the claims, the term "heterocycloalkyl" is not clear. What is it? Is it heterocycle substituted by alkyl e.g. alkylene-pyridine or a carbocycle substituted by a heteroatom e.g. -NH-cyclohexane?

b. In claim 1 (page 256, line 24) or elsewhere in the claims, the phrase "heterocyclic groups" is indefinite. What is the number and nature of the heteroatoms? Can the ring be fused or spiroconnected to another ring, and if so, what kind of ring? Can the ring be bridged? Unsaturated? Cf *In re Wiggins*, 179 USPQ 421, 423.

c. Claims 180-182 provides for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what

method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 180-182 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
March 31, 2003